

2. Aug. 2007 8:13

PEARL COHEN ZEDEK LATZER

RECEIVED
CENTRAL FAX CENTER

No. 3733 P. 5

AUG 02 2007

Please type a plus sign (+) inside this box ?

+

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|---|--------------------------|----------------------|
| Substitute for form 1449A/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/747,888 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1615 |
| | | Examiner Name | Not yet known |
| Sheet | 1 | of | 9 |
| | | Attorney Docket Number | P-2769-US9 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|----------|----------------------|-----------------------------------|---|--|---|
| Examiner Initials* | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
| | A | 4,990,538 | | Harris et al. | February 5, 91 | |
| | B | 5,788,884 | | Beral et al. | August 4, 98 | |
| | C | 5,630,425 | | Biegnon et al. | July 22, 97 | |
| | B | 4,696,849 | | Talvola et al. | Sept 29, 87 | |
| | E | 6,491,173 | | Talvola et al. | Feb. 18, 1998 | |
| | F | 6,674,684 | | Jelenen et al. | Nov. 5, 1998 | |
| | G | 5,605,700 | | DeGregorio et al. | Feb. 25, 1997 | |
| | H | 5,585,722 | | Grainger et al. | Jan. 21, 1997 | |
| | I | 5,599,844 | | Grainger et al. | Feb. 4, 1997 | |
| | J | 5,829,007 | | Audia et al. | May 13, 1997 | |
| | K | 5,635,187 | | Audia et al. | June 3, 1997 | |
| | L | 5,595,985 | | Labone | Jan. 21, 1997 | |
| /BFI/ | M | 5,441,988 | | Thompson, et al | 08-15-1995 | |
| | N | 5,852,059 | | Thompson, et al | 12-22-1998 | |
| | O | 5,827,892 | | Loeser, et al | 10-27-1998 | |
| | P | 5,821,254 | | Sporn, et al | 10-13-1998 | |
| | Q | 5,859,045 | | Treppendahl, et al | 01-12-1999 | |
| | R | 5,935,887 | | Treppendahl, et al | 08-10-1999 | |
| /BFI/ | S | 2005/0171073 | | Steiner, et al | 01-2006 | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|----------|-------------------------|---------------------|---|--|---|
| Examiner Initials* | Cite No. | Foreign Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Office ² | Number ² | Kind Code ³ (if known) | | |
| | T | WO | 88/58834 | | December 30, 88 | |
| | U | EP | 415 623 A2 | Harris et al | March 6, 1991 | |
| | V | EP | 616 529 B1 | | September 28, 94 | |
| | W | EPC | 095875 | | Dec 7, 1995 | |
| | X | WO | 95/28720 | Biegnon et al | Oct 12, 1995 | |
| | Y | WO | 0008001 | | Feb 17, 2000 | |

| | | | |
|--------------------|-------------------|-----------------|------------|
| Examiner Signature | /Blessing Fubara/ | Date Considered | 08/16/2007 |
|--------------------|-------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box ?



8/02/07

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0851-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|--------|-------------------------------|----------------------|
| Substitute for form 1449A/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10747,888 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1615 |
| | | Examiner Name | Not yet known |
| Sheet | 2 of 8 | Attorney Docket Number | P-2769-US9 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
| | Z | 4,329,364 | | Neri et al. | May 11, 1982 | |
| | AA | 4,474,813 | | Neri et al. | Oct. 2, 1984 | |
| | AB | 6,080,877 | | Swindell et al | June, 2000 | |
| | AC | 6,265,448 | | Steiner et al | July 24, 2001 | |
| | AD | 6,410,043 | | Steiner et al | June 25, 2002 | |
| | AE | 6,632,447 | | Steiner et al | Oct 14, 2003 | |
| | AF | 6,413,533 | | Steiner et al | July 2, 2002 | |
| | AG | 6,413,534 | | Steiner et al | July 2, 2002 | |
| | AH | 6,413,535 | | Steiner et al | July 2, 2002 | |
| | AI | 4,998,225 | | Toivola et al | Feb 26, 1991 | |
| | AJ | 5,811,420 | | Gibson et al | Sept 22, 1998 | |
| | AK | 5,972,383 | | Gibson et al | Oct 26, 1999 | |
| | AL | 4,418,068 | | Jones | Nov 29, 1983 | |

| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|-----------|-------------------------|---------------------|-----------------------------------|---|--|---|---|
| Examiner Initials* | Cite, No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T |
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | AM | WO | 94/12162 | | Warri et al | June 9, 1994 | | |
| | AN | WO | 99/58739 | | Steiner et al | November 11, 1999 | | |
| | AO | WO | 00/47214 | | Healey et al | August 17, 2000 | | |
| | AP | WO | 98/09046 | | Audia et al | March 28, 1998 | | |
| | AQ | EP | 0 670 162 | | Gibson et al | Sept 6, 1995 | | |
| /BF/ | AR | WO | 00/19928 | | KGK Synergize | 04-13-2000 | | |
| /BF/ | AS | WO | 97/25038 | | Novo Nordisk | 7-17-1997 | | |
| /BF/ | AT | WO | 99/08682 | | Duke University | 02-23-1999 | | |
| /BF/ | AU | WO | 97/25037 | | Novo Nordisk | 7-17-1997 | | |

| | | | |
|---------------------------|-------------------|------------------------|------------|
| Examiner Signature | /Blessing Fubara/ | Date Considered | 08/16/2007 |
|---------------------------|-------------------|------------------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

crossed out references previously considered on 1/07/2007

Please type a plus sign (+) inside this box ?



8/02/07

PTO/SB/08A (10-86)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|--------|-------------------------------|----------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/747,888 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1615 |
| | | Examiner Name | Not yet known |
| Sheet | 3 of 9 | Attorney Docket Number | P-2769-U88 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|----------|--|--------------------------|
| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | 1 ² |
| | AV | Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107. | <input type="checkbox"/> |
| | AW | Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5. | <input type="checkbox"/> |
| | AX | Kellogg et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 161: 1-8. | <input type="checkbox"/> |
| | AY | Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin D Analogue Ro24-5531 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627. | <input type="checkbox"/> |
| | AZ | Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442. | <input type="checkbox"/> |
| | BA | Schneider Martin R. et al. "Nonsteroidal Antiestrogens and Partial Estrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265. | <input type="checkbox"/> |
| | BB | Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antiestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J Steroid Biochem. Molec. Biol. Vol 64, No. 3-4, pp. 199-205, 1998. | <input type="checkbox"/> |
| | BC | Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response to Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18. | <input type="checkbox"/> |
| | BD | Richard Gams, MD "Phase III Trials of Toremifene vs. Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997 | <input type="checkbox"/> |
| | BE | Christian Rohlf et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen is Associated With Inhibition of Protein Kinase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc | <input type="checkbox"/> |
| | BF | Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Res., vol. 53, no. 21, 1993, pages 5199-5207, X00021 17653. | <input type="checkbox"/> |
| | BG | Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691. | <input type="checkbox"/> |
| | BH | Gingrich et al., "Pathologic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75. | <input type="checkbox"/> |
| | BI | Gingrich et al., "Metastatic Prostate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102. | <input type="checkbox"/> |
| | BJ | Gershonovich et al., "A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262. | <input type="checkbox"/> |

| | | | |
|---------------------------|-------------------|------------------------|------------|
| Examiner Signature | /Blessing Fubara/ | Date Considered | 08/16/2007 |
|---------------------------|-------------------|------------------------|------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

crossed out references previously considered on 1/07/2007

Please type a plus sign (+) inside this box ?



8/02/07

PTO/SB/08A (10-98)

Approved for use through 10/31/99. OMB 0851-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|--------|-------------------------------|----------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/747,888 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1815 |
| | | Examiner Name | Not yet known |
| Sheet | 4 of 8 | Attorney Docket Number | P-2768-U89 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | 1 ² |
| | BK | Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of Toremifene in Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 13, No. 10, 1995, pages 2556-2566. | |
| | BL | Pyrhonen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with Advanced Breast Cancer: a Randomized Double-blind, the 'Nordic' Phase III Study", British Journal of Cancer, 1997, 76(2), pages 270-277. | |
| | BM | Neubauer et al., "Endocrine and Antiproliferative Effects of Raloxifene (LY136758) in the Male Rat", The Prostate 23, 1993, pages 245-262. | |
| | BN | Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39, 1999, pages 305-309. | |
| | BO | Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144. | |
| | BP | Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40. | |
| | BQ | Hietanen T "Open Phase II Study of High Dose Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4): 37-40. | |
| | BR | Black et al. "Uterine Bioassay of Tamoxifen, Toremifene and a New Estrogen Antagonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458 | |
| | BS | Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 17 β -Estradiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357. | |
| | BT | Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4-Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994) | |
| | BU | Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106. | |
| | BV | Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III Prostate Cancer, pages 467-477 | |
| | BW | Jordan MC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271 | |
| | BX | Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toremifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66. | |
| | BY | Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Trials" Oncology (Huntingt) 1998 Mar; 12(3 Suppl 5): 28-31. | |
| | BZ | Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93. | |

| | | | |
|---------------------------|-------------------|------------------------|------------|
| Examiner Signature | /Blessing Fubara/ | Date Considered | 08/16/2007 |
|---------------------------|-------------------|------------------------|------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

crossed out references previously considered on 1/07/2007

Please type a plus sign (+) inside this box ?



8/02/07

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0851-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|---|-------------------------------|----------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10747,686 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1815 |
| | | Examiner Name | Not yet known |
| Sheet | 8 | of | 8 |
| | | Attorney Docket Number | P-2769-US9 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|----------|--|--|
| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | |
| | CA | Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88. | |
| | CB | Hoekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5-6): 888-94. | |
| | CC | Brandes LJ et al. "Salutary Clinical Response Of Prostate Cancer To Antandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paradigm Predictive Of Tumor Growth Enhancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61. | |
| | CD | Miyata E et al. "Effects Of Tamoxifen, An Antiestrogen, On Rat Prostate Carcinogenesis by 3,2'-Dimethyl-4-Aminobiphenyl And Testosterone Do Not Support An Estrogen Role In Testosterone Promotion", Prostate 1997 Apr 1; 31(1)9-13. | |
| | CE | Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate", Am J Clin Oncol 1996 Oct; 19(5):500-3. | |
| | CF | Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate 1995 May; 26(5): 270-4. | |
| | CG | Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73. | |
| | CH | Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79. | |
| | CI | Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone-Refractory Prostate Cancer.", Clin Cancer Res 1999 Sep; 5(9): 2366-73. | |
| | CJ | Chang William Y et al. "Estrogen Receptor-? : Implications For The Prostate Gland" The Prostate 40:115-124 (1999) | |
| | CK | Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-? (Er-?) And ? (Er-?) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract" Steroids 63: 498-504, 1998, Elsevier Science Inc. | |
| | CL | Prins Gail S. et al. "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression In The Developing And Adult Rat Prostate Lobes", Endocrinology 138: 1801-1809 (1997) | |
| | CM | Hampstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto-Oestrogens", British Journal Of Urology (1998), 82, 560-563. | |
| | CN | Awoniyi Caleb A. et al. "Neonatal Exposure To Coumestrol, A Phytoestrogen, Does Not Alter Spermatogenic Potential In Rats", Endocrine, vol. 7, no. 3, 337-341, December 1997. | |
| | CO | "Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", Journal of Cellular Biochemistry, Supplement 161:140-145 (1992). | |

| | | | |
|---------------------------|-------------------|------------------------|------------|
| Examiner Signature | /Blessing Euhara/ | Date Considered | 08/16/2007 |
|---------------------------|-------------------|------------------------|------------|

* EXAMINER: Initial & reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

crossed out references previously considered on 1/07/2007

Please type a plus sign (+) inside this box ?



8/02/07

PTO/SB/08A (10-98)

Approved for use through 10/31/99. OMB 0851-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|------------------------|--------------------------|----------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/747,888 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1615 |
| | | Examiner Name | Not yet known |
| Sheet 8 of 9 | Attorney Docket Number | P-2769-US9 | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|----------|--|--|
| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | |
| | CP | "When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 1611:138-139 (1992). | |
| | CQ | "Editorial: A New Actor In The Estrogen Receptor Drama-Intre ER-?", Endocrinology Vol. 138, No. 3, (1997). | |
| | CR | Kulper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcriptional Distribution Of Estrogen Receptors α and β ", Endocrinology Vol. 138, No. 3, 863-870 (1997). | |
| | CS | Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Oestrogens" Breast Cancer Research and Treatment 31: 5-9, 1994. | |
| | CT | Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme. | |
| | CU | Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3):291-300. | |
| | CV | Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7. | |
| | CW | Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399. | |
| | CX | Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35. | |
| | CY | Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161, 1748-1760, June 1999, p. 1748-1760. | |
| | CZ | Hleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52 | |
| | DA | Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618 | |
| | DB | Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 889-894 (1994) | |
| | DC | Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106. | |

| | | | |
|--------------------|-------------------|-----------------|------------|
| Examiner Signature | /Blessing Fubara/ | Date Considered | 08/16/2007 |
|--------------------|-------------------|-----------------|------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

crossed out references previously considered on 1/07/2007

Please type a plus sign (+) inside this box ?



8/02/07

PTO/SB/08A (10-98)

Approved for use through 10/31/99. OMB 0861-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|---|--------------------------|----------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/747,686 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1616 |
| | | Examiner Name | Not yet known |
| | | Attorney Docket Number | P-2769-US9 |
| Sheet | 7 | of | 9 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|----------|---|----------------|
| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | 1 ² |
| | DD | Cheng U et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71. | |
| | DE | Bonkhoff H et al. "Estrogen Receptor Expression In Prostate Cancer and Premalignant Prostatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999. | |
| | DF | "New Research Approaches In The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research, December 1998 | |
| | DG | Xiaolin Zi et al. "Silibinin Decreases Prostate-Specific Antigen With Cell Growth Inhibition Via G1 Arrest, Leading To Differentiation Of Prostate Carcinoma Cells: Implications For Prostate Cancer Intervention", Proc. Natl. Acad. Sci, USA Vol. 96, pp. 7490-7495, June 1999. Medical Sciences. | |
| | DH | Landstrom M, et al. "Inhibitory Effects Of Soy and Rye Diets On The Development Of Dunning R3327 Prostate Adenocarcinoma In Rats, The Prostate 36: 151-161 (1998). | |
| | DI | Huelke-Sum J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21. | |
| | DJ | Freinen KA et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction In Rats And Rabbits", Toxicol Sci 1998 Feb; 41(2):199-207. | |
| | DK | Buchm S et al. "Estrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Prostatic Hyperplasia: Evidence For Its Efficacy From Studies With Mepantrich" Wien Klin Wochenschr 1998 Dec 11; 110(23):817-23. | |
| | DL | Dhar JI et al. "Estrogen, Androgen and Antiestrogen Responses In The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69. | |
| | DM | West Neal B et al. "Estrogen and Progesterone Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. L. 123, (1998) | |
| | DN | Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998) 83-93, Elsevier Science Ireland Ltd. | |

| | | | |
|--------------------|-------------------|-----------------|------------|
| Examiner Signature | /Blessing Fubara/ | Date Considered | 08/16/2007 |
|--------------------|-------------------|-----------------|------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

crossed out references previously considered on 1/07/2007

Please type a plus sign (+) inside this box ?



8/02/07

PTO/SB/08A (10-88)

Approved for use through 10/31/99. OMB 0851-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|------------------------|--------------------------|----------------------|
| Substitute for form 1449B/PTO | | Complete If Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/747,688 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1616 |
| | | Examiner Name | Not yet known |
| Sheet 8 of 9 | Attorney Docket Number | P-2769-US9 | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|----------|--|----------------|
| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | DO | Hobisch Alfred "Metastatic Lesions From Prostate Cancer Do Not Express Oestrogen And Progesterone Receptors" J. Pathol. 182: 356-361, 1997. | |
| | OP | Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overview of Diet Cancer 6928-6975 (1995) | |
| | DQ | Strom Sam S. et al. "Phytoestrogen Intake and Prostate Cancer: A Case-Control Study Using A New Database", Nutrition and Cancer, 33(1), 20-25. (1999). | |
| | DR | Kelloff GJ et al. "Strategies For Chemoprevention Of Prostate Cancer", Prostate Cancer and Prostate Disease (1988) 5: 107. | |
| | DS | Buckle-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998. | |
| | DT | Prins Carl S. "Developmental Estrogenization Of The Prostate Gland", Prostate: Basic and Clinical Aspects p. 245-263 (1997). | |
| | DU | Kuiper George G. J. M. "Cloning Of A Novel Estrogen Receptor Expressed In Rat Prostate And Ovary", Proc. Natl. Acad. Sci USA Vol. 93, pp. 5925-5930, June 1996 Biochemistry. | |
| | DV | Kuiper George G. J. M. "Interaction Of Estrogenic Chemicals and Phytoestrogens With Estrogen Receptor?", Endocrinology Vol. 139, No. 10 (1998). | |
| | DW | Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988). | |
| | DX | Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antagonist (LY117018) In Rats And Mice" In Life Sciences, 1980, vol. 26, pp. 1453-1458. | |
| | DY | Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998 | |
| | DZ | Warri Anni. M. et al "Apoptosis in Toremifene Induced Growth Inhibition of Human Breast Cancer Cells in Vivo and In Vivo" Journal of National Cancer Institute, Vol. 85, No. 17, September 1, 1993 | |
| | EA | Mobbs, B.G. et al "Concentration and Cellular Distribution of Androgen Receptor In Human Prostatic Neoplasia: Can Estrogen Treatment Increase Androgen Receptor Content?" J. Steroid Biochem. Vol. 19, No. 3 pp. 1279-1290, 1983. | |

| | | | |
|--------------------|-------------------|-----------------|------------|
| Examiner Signature | /Blessing Fubara/ | Date Considered | 08/16/2007 |
|--------------------|-------------------|-----------------|------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

crossed out references previously considered on 1/07/2007

Please type a plus sign (+) inside this box ?



8/02/07

PTO/SB/08A (10-88)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|------------------------|--------------------------|----------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10747,686 |
| | | Filing Date | December 30, 2003 |
| | | First Named Inventor | STEINER, Mitchell S. |
| | | Group Art Unit | 1615 |
| | | Examiner Name | Not yet known |
| Sheet 9 of 9 | Attorney Docket Number | P-2769-US9 | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|----------|--|---|
| Examiner Initials* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | † |
| | EB | Krieg, Michael et al "Androgens and Estrogens: Their Interaction with Stroma and Epithelium of Human Benign Prostatic Hyperplasia and Normal Prostate" J. Steroid Biochem. Vol. 19, No. 1 pp. 155-161, 1983 | |
| | EC | Hard, Gordon C. et al "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toramifene and Tamoxifen in Female Crl: CD(BR) Rats" Cancer Research 53, 4534-4541, October 1, 1993 | |
| | ED | Boyle Peter et al "Epidemiology of Prostate Cancer Chemoprevention" Eur Urol 1999: 35:370-376 | |
| | EE | Bostwick, David G. et al "Reversibility of Prostatic Intraepithelial Neoplasia: Implications for Chemoprevention" Eur. Urol 1999: 35:492-495 | |
| | EF | Bostwick David "Prospective Origins of Prostate Carcinoma" American Cancer Society 1996 | |
| | EG | The Lancet "The Challenge of Breast Cancer" Vol. 342, September 18, 1993 | |
| | EH | Zaridze, David G. et al "International Trends in Prostatic Cancer" Int. J. Cancer; 33, 223-230 (1984) | |
| | EI | Nevolaianen MT et al "Hormone regulation of human prostate in organ culture" Cancer Res 1993 Nov 1;53 (21):5199-207 | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| | | | |
|--------------------|-------------------|-----------------|------------|
| Examiner Signature | /Blessing Eubara/ | Date Considered | 08/16/2007 |
|--------------------|-------------------|-----------------|------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

† Unique citation designation number. ‡ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

crossed out references previously considered on 1/07/2007